the remaining claims, amendments thereto address the objections raised by the Examiner under 35 U.S.C. 101 and 112 with regard to them.

On the merits, it should be noted initially that, before the invention, 100% detection* of Salmonella, while desired, was difficult to achieve as is evidenced by the prior art.

In this regard, WO 95/00 664 to Holmes reference is made to the discussion in the application in question English page 2 last paragraph to page 3 para. 2. From Holmes table 1 can be seen that primers ST1 to 8 lead to false-negative results. Further, in some cases false-positive results were obtained. The results with the primer combination ST11/ST15 lead to incomplete results since, for example, not all of the Salmonella arizonae strains could be detected; cf. table 2. According to this table 144 of 146 Salmonella strains were detected which corresponds to a failure rate of 1.4 %. Such a failure

* The Council Directive 92/118/EEC of 17 December 1992 is attached. From chapter 6 (I)(B)(1)(c) to (d) can be drawn that tests for Salmonella in processed animal protein must be negative. Chapter 6 (V) defines measures to be taken if processed animal protein proves to be positive for Salmonella. Chapter 14 prescribes the absence of Salmonella even in soil (25 g of treated product).

rate can, however, not be accepted in the fields of public health and foodstuffs.

Example 3 compares a PCR-system for Salmonella with a culturing method. This comparison shows also a significant gap for the PCR-system since at least 1 % of the results are false-negative; cf. page 28 line 30.

It should be noted that the specificity is a parameter which depends on the sequence of a primer. In other words, if PCR-reaction conditions are modified, the specificity of a primer cannot be increased if the target-DNA to be detected is different. This is also clear from table 1 of Holmes, since in most cases an adaption of the reaction conditions does not exclude false-negative results.

Accordingly, in view of the foregoing, the results presented by Holmes are would not provide motivation to a skilled worker in the art as the Examiner suggests on pages 8 and 9 of the action. Rather, Holmes would be demotivating to a skilled worker in view of the absence reliability of a detection system for Salmonella.

Turning now to U.S. Patent 5,714,321 to Hogan, this reference concerns a detection of Salmonella by means of target molecules of the ribosomal operon (16S rRNA). This

is a striking difference between Hogan and the present application which is directed to a different target molecule. Experimental data for the specificity of primers derived from a ribosomal operon can be seen in Hogan table 50. It is obvious that several species or serotypes could be detected by means of the probes merely with a very low affinity. This applies especially to Salmonella sp. serotype harmelen (5.8 and 8.0 %, respectively). Further it should be noted that the detection of Salmonella typhi shows a relatively low affinity (7.0 and 21 %, resp.) and is thus not clear.

Further, Hogan did not show the results could be transferred to a detection method using PCR. Hogan table 50 shows a use of oligonucleotides merely as probe. It is clear, that a precondition of a PCR is the use of at least two primers. As regards a detection, at least one additional probe is necessary. Both primers must have a comparable high degree of specificity. The fact that the hybridization degree according to Hogan can be as low as 1.4 % for S. paratyphi A as a species to be detected and as high as 2.2 % for Citrobacter freundii as a species not to be detected (tables 50 and 51) in the understanding of claim 21 is demotivating for a search for 2

primers which **both** offer a high specificity for Salmonella species.

In summary, in viewing the data of Holmes, a skilled worker in the art interested in a 100 % Salmonella-detection system would be demotivated rather than motivated before the present invention.

Furthermore, it is completely unexpected that within the practically unlimited number of conceivable primer candidates of SEQ ID No. 1 of Holmes some primers could be elected, which really fulfill the requirement of a 100 % detection system for all Salmonella stains.

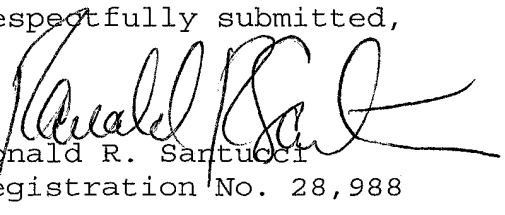
In this regard, reference is made to the present specification's table 1a. As regards the 296 strains which comprise all 7 Salmonella species and which have been subjected to a test, all these strains could be detected by PCR and, in addition, by hybridization. False-positive results have not occured.

Lastly, accompanied herewith is the declaration of Dr. Pia Scheu which confirms a 100 % specificity of the claimed PCR detection system.

It is submitted that the claims are patentably distinct from the art cited and, accordingly, a notice of allowance is earnestly solicited.

The Commissioner is authorized to charge any additional fees that may be required to Deposit Account No. 501145, Order No. 2727-100J.

Respectfully submitted,



Ronald R. Santucci
Registration No. 28,988

(212)687-6000
Pitney, Hardin, Kipp and Szuch, LLP
711 Third Avenue, 20th Floor
New York, New York 10017

APPENDIX:

7. (Twice Amended) A nucleic [Nucleic] acid molecule that belongs to a set of nucleic acid molecules by means of which, in a process for the detection of representatives of *Salmonella enterica* subsp. *enterica, salamae, arizonae, diarizonae, houtenae, bongori* and *indica*, all the representatives of those subspecies can be detected, [according to claim 1] or nucleic acid molecule that can be used for such a set, wherein [characterised in that], in a region of at least 10 successive nucleotides of its nucleotide chain, the sequence of the nucleic acid molecule corresponds exactly to a sequence region of at least one representative of the *Salmonella enterica* subspecies [according to claim 1], the sequence region comprising or being a phylogenetically conserved base sequence or a region of that base sequence, wherein in a region of at least 10 successive nucleotides of its nucleotide chain, it is 100% or at least 80% identical to a corresponding number of successive nucleotides of one or more of the following sequences or their complementary sequences:

SEQ ID NO: 1 ATGGATCAGAATACGCCCCG

SEQ ID NO: 2 ATGGATCAGAATACACCCCG

SEQ ID NO: 3 CAGAATACGCCCCGTTCGGC

SEQ ID NO: 4 CAGAATACACCCCGTTCGGC

SEQ ID NO: 5 CAGAATACGCCCCGTTCAGC

SEQ ID NO: 6 CAACCTAACTTCTGCGCCAG

SEQ ID NO: 7 CAACCTAACTTCTGCACCAG

SEQ ID NO: 8 CAACCTAACCTCTGCGCCAG

SEQ ID NO: 9 CAACCTAACTTCTGCGGCAG

SEQ ID NO: 10 CAGCCTAACTTCTGCGCCAG.

9. (Twice Amended) The nucleic [Nucleic] acid molecule which [characterised in that], in respect of it sequence, [it] is homologous to a nucleic acid molecule according to claim 7 and, in at least 10 successive nucleotides of its nucleotide chain,

(i) is identical to a nucleic acid molecule according to claim 7, or

(ii)differs from a nucleic acid molecule according to claim 7 in not more than one nucleotide, or

(iii)differs from a nucleic acid molecule according to claim 7 in not more than two nucleotides.

10. (Twice Amended) The nucleic [Nucleic] acid molecule according to claim 7, which [characterised in that it] is

from 10 to 250 nucleotides long[, and preferably from 15 to 30 nucleotides long].

11. (Twice Amended) The nucleic [Nucleic] acid molecule according to claim 7[, characterised in that it] is single-stranded or has a complementary strand.

12. (Twice Amended) The nucleic [Nucleic] acid molecule according to claim 7, which [characterised in that it] is present

(i) as DNA, or

(ii) as RNA corresponding to (i), or

(iii)as PNA, the nucleic acid molecule where appropriate having been modified or labelled in a manner known *per se* for analytical detection processes[, especially detection processes based on hybridisation and/or amplification].

13. (Amended) The nucleic [Nucleic] acid molecule according to claim 12, which [characterised in that it] is a modified or labelled nucleic acid molecule in which up to 20% of the nucleotides of at least 10 successive nucleotides of its nucleotide chain are building blocks

known *per se* as probes [and/]or primers[, especially nucleotides that do not occur naturally in bacteria].

14. (Twice Amended) The nucleic [Nucleic] acid molecule according to claim 12, which [characterised in that it] is a modified or labelled or additionally modified or labelled nucleic acid molecule that comprises, in a manner known *per se* for analytical detection processes, one or more radioactive groups, coloured groups, fluorescent groups, groups for immobilisation on a solid phase, groups for an indirect or direct reaction[, especially for an enzymatic reaction, preferably using antibodies, antigens, enzymes and/or substances having an affinity for enzymes or enzyme complexes, and/]or other modifying or modified groups of nucleic-acid-like structure that are known *per se*.

15. (Twice Amended) A kit [Kit] for analytical detection processes, for the detection of bacteria of the *Salmonella* genus, comprising [characterised by

(i) a set of nucleic acid molecules according to claim 1, or

(ii)] one or more nucleic acid molecules according

to claim 7.

16. (Amended) The kit [Kit] according to claim 15, wherein [characterised in that] the set of nucleic acid molecules was produced synthetically and that it was produced in at least two separate synthesis batches.

17. (Amended) The kit [Kit] according to claim 16, wherein [characterised in that] the kit does not comprise any degenerate nucleic acid molecules.

18. (Twice Amended) A method of detecting the presence or absence of a bacteria comprising the step of using [Use of] a set of [nucleic acid molecules according to claim 1, of] one or more nucleic acid molecules according to claim 7 or of a kit according to claim 15 to detect the presence or absence of bacteria belonging to representatives of *Salmonella enterica* subspecies according to claim 7 [1].

19. (Amended) The method [Use] according to claim 18, wherein a step selected from the group consisting of [characterised in that] nucleic acid hybridization

[hybridisation] and[/or] nucleic acid amplification is carried out.

20. (Amended) The method [Use] according to claim 19, wherein [characterised in that] a polymerase chain reaction (PCR) is carried out as nucleic acid amplification.

21. (Twice Amended) The method [Use] according to claim 18, wherein [characterised in that] differences between the genomic DNA and/or RNA of the bacteria to be detected and of the bacteria that are not to be detected are determined at at least one nucleotide position in the region of a nucleic acid molecule according to claim 7 and representatives of a group of bacteria of the *Salmonella* genus are detected[, especially representatives of *Salmonella enterica* subspecies according to claim 1].

APPENDIX (CONT.)

New claims 22-27:

--22. (New) The nucleic acid molecule according to claim 10, which is from 15 to 30 nucleotides long.

23. (New) The nucleic acid molecule according to claim 12, which is present

(i) as DNA, or

(ii) as RNA corresponding to (i), or

(iii) as PNA, the nucleic acid molecule where appropriate having been modified or labelled in a manner known *per se* for analytical detection processes based on hybridisation and/or amplification.

24. (New) The nucleic acid molecule according to claim 13, which is a modified or labelled nucleic acid molecule in which up to 20% of the nucleotides of at least 10 successive nucleotides of its nucleotide chain are nucleotides that do not occur naturally in bacteria.

25. (New) The nucleic acid molecule according to claim 14 which is a modified or labelled or additionally modified or labelled nucleic acid molecule that comprises, in a

manner known *per se* for analytical detection processes, one or more radioactive groups, coloured groups, fluorescent groups, groups for immobilisation on a solid phase, groups for an indirect or direct enzyme reaction.

26. (New) The nucleic acid molecule according to claim 14 which is a modified or labelled or additionally modified or labelled nucleic acid molecule that comprises, in a manner known *per se* for analytical detection processes, one or more radioactive groups, coloured groups, fluorescent groups, groups for immobilisation on a solid phase, groups for an indirect or direct reaction using antibodies, antigens, enzymes or substances having an affinity for enzymes or enzyme complexes.

27. (New) The method according to claim 21, wherein representatives of *Salmonella enterica* subspecies according to claim 7 are detected.--

OIPE JC59
JUN 18 2001
PATENT & TRADEMARK OFFICE

To the United States Patent and Trademark Office

In response to Art unit 1655 of 03/14/01 of Application of

Application NO.: 09/485,434

Filing Date: 04/14/00

Title: Nucleic acid molecule set for detecting Salmonella, nucleic acids, kit and use

Declaration:

Dr. Pia Scheu declares:

That she is a citizen of Germany, residing in Berlin, Germany, to which the application identified above has been assigned.

She has carried out the following examples:

Table 1: The following Salmonella strains have been tested positively with the foodproof™ PCR-System of BIOTECON Diagnostics. The detection system was 100% specific in that each strain among the 560 tested was identified as belonging to the genus Salmonella.

Table 1:

	number of isolates
Salmonella species	**tested**
Salmonella enterica	
Subspecies enterica (I)	
Serogroup A	1
Serogroup B	120
Serogroup C	127
Serogroup D	79
Serogroup E	38
Serogroup F	9
Serogroup G	8
Serogroup H	5
Serogroup I	4

12.JUN.2001 18:45 +49 89 653962 BOETERS & BAUER #1852 P.017

OIPE JC59
JUN 18 2001
PATENT & TRADEMARK OFFICE

Salmonella species	number of isolates tested
Serogroup J	1
Serogroup K	1
Serogroup L	3
Serogroup M	10
Serogroup N	3
Serogroup O	5
Serogroup P	4
Serogroup Q	1
Serogroup R	1
Serogroup S	2
Serogroup T	1
Serogroup U	1
Serogroup V	3
Serogroup W	1
Serogroup X	2
	430
Salmonella enterica	
Subspecies salamae (II)	
Serogroup B	2
Serogroup C	2
Serogroup F	2
Serogroup I	2
Serogroup J	2
Serogroup L	2
Serogroup P	2
Serogroup R	2
Serogroup S	2
Serogroup T	6
Serogroup X	5
Serogroup Z	5
Serogroup O : 58	1
	35

OIPE JC59
JUN 18 2001
PATENT & TRADEMARK OFFICE

	number of isolates
Salmonella species	**tested**
Salmonella enterica	
Subspecies arizonae (III a)	
Serogroup J	**2**
Serogroup K	**2**
Serogroup P	**2**
Serogroup R	**1**
Serogroup S	**2**
Serogroup U	**1**
Serogroup V	**2**
Serogroup Y	**4**
Serogroup Z	**1**
Serogroup O : 51	**2**
Serogroup O : 53	**2**
Serogroup O : 62	**2**
Serogroup O : 63	**1**
	24
Salmonella enterica	
Subspecies diarizonae (III b)	
Serogroup D	**2**
Serogroup I	**2**
Serogroup J	**2**
Serogroup O	**2**
Serogroup P	**2**
Serogroup T	**2**
Serogroup X	**4**
Serogroup Y	**2**
Serogroup Z	**2**
Serogroup O : 53	**2**
Serogroup O : 60	**1**
Serogroup O : 61	**4**
	27

OIPE JC56
JUN 18 2001
PATENT & TRADEMARK OFFICE

Salmonella species	number of isolates tested
Salmonella enterica	
Subspecies houtenae (IV)	
Serogroup F	2
Serogroup I	4
Serogroup J	2
Serogroup K	2
Serogroup L	2
Serogroup U	3
Serogroup V	3
Serogroup Y	2
Serogroup Z	2
	22
Salmonella enterica	
Subspecies bongori (V)	
Serogroup R	5
Serogroup V	5
Serogroup Y	4
	14
Salmonella enterica	
Subspecies indica (VI)	
Serogroup S	2
Serogroup W	2
Serogroup Y	4
	8
Sum	560

OIPE JC89
JUN 18 2001
PATENT & TRADEMARK OFFICE

Table 2 is a summary of table 1. Reference is given to the names of the subspecies of Salmonella enterica and Salmonella bongori. All 560 strains have been tested positive with the BIOTECON Diagnostics foodproof™ PCR-System.

Table 2:

Salmonella species	Number of strains tested
Salmonella enterica Subspecies enterica (I)	430
Salmonella enterica Subspecies salamae (II)	35
Salmonella enterica Subspecies arizonae (IIIa)	24
Salmonella enterica Subspecies diarizonae (IIIb)	27
Salmonella enterica Subspecies houtenae (IV)	22
Salmonella enterica Subspecies indica (VI)	8
Salmonella bongori (V)	14
	560

12.JUN'2001 18:45 +49 89 653962 BOETERS & BAUER #1852 P.021

OIPE JC
JUN 18 2001
PATENT & TRADEMARK OFFICE

Table 3 gives reference to the serotypes of the strains shown in table 1 and table 2.

Table 3:

Sub-species	Sero-gr.	Salmonella Sero type
S. enterica subsp. *enterica*	A	Kiel
	B	Abortusovis
		Africana
		Agona (12 Isolate)
		Arechavaleta
		Brandenburg (12 Isolate)
		Bredeney
		Chester
		Coeln
		Derby (14 Isolate)
		Duisburg (2 Isolate)
		Heidelberg (2 Isolate)
		I 4, 12: d: -
		I 4, 12:-:-
		I 9, 12: l, v: -
		Indiana
		Kiambu
		Kunduchi
		Paratyphi B (8 Isolate)
		Reading
		Saintpaul O5 - (2 Isolate)
		Sandiego
		Schleisheim
		Schwarzengrund
		Stanley
		Stanleyville
		Typhimurium (50 Isolate)
	C	Augustenborg
		Bareilly
		Braenderup
		Choleraesuis
		Choleraesuis var. Decatur
		Choleraesuis var. Kunzendorf
		Colindale

Sub-species	Sero-gr.	Salmonella Sero type
		Livingstone (12 Isolate)
		Mbandaka
		Mikawasima
		Montevideo (6 Isolate)
		Ohio
		Oranienburg
		Oslo
		Richmond (2 Isolate)
		Rissen
		Singapore
		Tennessee
		Thompson (2 Isolate)
		Virchow (11 Isolate)
		I 6, 7 : - : - (2 Isolate)
		Albany (2 Isolate)
		Altona
		Apeyeme
		Bardo
		Blockley
		Bovismorbificans (12 Isolate)
		Charlottenburg
		Cottbus
		Emek
		Ferruch
		Glostrup
		Goldcoast
		Haardt
		Hadar (12 Isolate)
		Kentucky
		Litchfield
		Manchester
		Manhatten (11 Isolate)
		Molade
		München

OIPE JC56
JUN 18 2001
PATENT & TRADEMARK OFFICE

Sub-species	Sero-gr.	Salmonella Sero type
		Concord
		Infantis (12 Isolate)
		Isangi
		Lille

Sub-species	Sero-gr.	Salmonella Sero type
		Newport (6 Isolate)
		Takoradi
		I 6, 8 : - : -
		I 8, 20 : - : -

Sub-species	Sero-gr.	Salmonella Sero type
	D	Dublin (6 Isolate)
		Durban
		Enteritidis (44 Isolate)
		Gallinarum
		Gallinarum-Pullorum
		Israel
		Javiana
		Kapemba
		Napoli
		Panama (8 Isolate)
		Pullorum (6 Isolate)
		I 9, 12 : - : -
		Typhi (5 Isolate)
		Plymoth
	E	Amager
		Amsterdam O : -, 15+, 34+
		Anatum (8 Isolate)
		Birmingham
		Butantan
		Falkensee
		Give
		Lexington
		London
		Meleagridis
		Münster (2 Isolate)
		Orion (2 Isolate)
		Sinstorf
		Stockholm
		Uganda (2 Isolate)
		Velle (2 Isolate)
		Weltevreden
		Westhampton
		Zanzibar
		I 3, 10 : - : 6 (monophasisch)

Sub-species	Sero-gr.	Salmonella Sero type
		I 1, 3, 19, : -: -
	F	Chandans (2 Isolate)
		Kisarawe
		Krefeld
		Liverpool
		Rubislaw
		Solt
		Telashomer
	G	Grumpensis
		Havana
		Idikan
		Kedougou
		Poona
		Putten
		Worthington
		I 13, 23, : -
	H	Caracas
		Charity
		Lindern
		Onderstepoort
		Sundsvall
	I	Gaminara
		Hvittingfoss
		Malstatt
		Saphra
	J	Bonames
	K	Cerro
	L	Minnesota (2 Isolate)
		Ruiru
	M	Cotham
		Guildford
		Ilala
		Loeben
		Mundonobo

OIPE JC59
JUN 18 2001
PATENT & TRADEMARK OFFICE

Sub-species	Sero-gr.	Salmonella Sero type
		I 10 : - : 1,6
		Abaetuba
		Aberdeen
		Cannstatt
		Llandoff
		Senftenberg (2 Isolate)

Sub-species	Sero-gr.	Salmonella Sero type
		Nima
		Patience
		Pomona
		Taunton
		Wedding
	N	Aqua

Sub-species	Sero-gr.	Salmonella Sero type
		Morningside
		Urbana
	O	Adelaide
		Alachua
		Ealing
		Haga
		Monschaul
	P	Lansing
		Roan (2 Isolate)
		Shettfield
	Q	Kokomelemle
	R	Johannesburg
	S	Waycross (2 Isolate)
	T	Waral
	U	Thetford
	V	Koketime (2 Isolate)
		Lawra
	W	Suelldorf
	X	I 47, z_4, z_{23} : - (monophasisch)
		Mountpleasant
S. enterica subsp. *salamae*	B	II 4, 12 : a : - (2 Isolate)
	C	II 6, 7 : d : 1,7 (2 Isolate)
	F	II 11 : g, m, s, t: z_{39} (2 Isolate)
	I	II 16 : g, m, s, t: - (2 Isolate)
	J	II 17 : c : z_{39}

Sub-species	Sero-gr.	Salmonella Sero type
		II 47 : b : 1,5 (2 Isolate)
		II 47 : b : z_9
	Z	II 50 : b : z_6 (5 Isolate)
	O:58	II 58 : l, z_{13}, z_{28}: z_6
S. enterica subsp. *arizonae*	J	IIIa 17 : z_4, z_{32}: - (2 Isolate)
	K	IIIa 18 : z_4, z_{23}: - (2 Isolate)
	P	IIIa 38 : l, v: - (2 Isolate)
	R	IIIa 40 : z_4, z_{24}: -
	S	IIIa 41: z_4, z_{23}: - (2 Isolate)
	U	IIIa 43 : g, z_{51}: -
	V	IIIa 44 : z_4, z_{32}: -
		IIIa 44 : z_{41}, z_{23}: -
	Y	IIIa 48 : (l): -
		IIIa 48 : g, z_{51}: -
		IIIa 48 : z_{36}: -
		IIIa 48 : z_4, z_{23}: -
	Z	IIIa 50 : z_4, z_{24} : -
	O:51	IIIa 51 : z_4, z_{23} : -
		IIIa 51 : g, z_{51}: -
	O:53	IIIa 53 : z_4, z_{23}, z_{32} : -
		IIIa 53 : z_{23} : -
	O:62	IIIa 62 : z_{36} : - (2 Isolate)
	O:63	IIIa 63 : g, z_{51} : -
S. enterica subsp. *diarizonae*	D	IIIb 1, 9, 12 : y : z_{39} (2 Isolate)
	I	IIIb 16 : k : - (2 Isolate)

OIPE JC59
JUN 18 2001
PATENT & TRADEMARK OFFICE

Sub-species	Sero-gr.	Salmonella Sero type
		II 17 : b : e, n, x, z_{15}
	L	II 21 : z_{10} : - (2 Isolate)
	P	II 38 : d : 1,5 (2 Isolate)
	R	II 1, 40 : z_{42}: 1,5,7 (2 Isolate)
	S	II 41 : z_{10}, 1, 2 (2 Isolate)
	T	II 42 : r : - (6 Isolate)
	X	II 47 : a : 1,5 (2 Isolate)

Sub-species	Sero-gr.	Salmonella Sero type
	J	IIIb 17 : z_{10}, e, n, x, z_{15} (2 Isolate)
	O	IIIb 35 : k: e, n, z_{15} (2 Isolate)
	P	IIIb 38 : l, v: z_{53}
		IIIb 38 : l, v: z_{54}
	T	IIIb 42 : k : z_{35} (2 Isolate)
	X	IIIb 47 : b : z_6
		IIIb 47 : k : z_{35}

Sub-species	Sero-gr.	Salmonella Sero type
		IIIb 47 : r: z_{53}
		IIIb 47 : - : -
	Y	IIIb 48 : (k) : z_{53} (2 Isolate)
	Z	IIIb 50 : k : z
		IIIb 50 : r : z
	O:53	IIIb 53 : l, k : z (2 Isolate)
	O:60	IIIb 60 : z_{52} : z_{53}
	O:61	IIIb 61 : l : z
		IIIb 61 : l, v : 1,5,7
		IIIb 61 : l, v : 1,5,7: (z_{57})
		IIIb 61 : r : z_{53}
S. enterica subsp. *houtenae*	F	IV 11 : z_4, z_{23}: - (2 Isolate)
	I	IV 16 : z_4, z_{32}: -(3 Isolate)
	I	IV 16 : z_4, z_{32}: - (2 Isolate)
	J	IV 17 : z_{29}: - (2 Isolate)
	K	IV 18 : z_{36}, z_{38}: - (2 Isolate)
	L	IV 21: g, z_{51}: - (3 Isolate)
	U	IV 43 : z_4, z_{23}: - (3 Isolate)
		IV 43 : z_4, z_{32}: -
	V	IV 44 : z_4, z_{32}: - (3 Isolate)
	Y	IV 48 : z_{29}: - (2 Isolate)
	Z	IV 50 : z_4, z_{23}:- (2 Isolate)
S. enterica subsp. *indica*	S	VI 41 : b: 1,7 (2 Isolate)
	W	VI 45 : a: e,n,x, (z_{17}) (2 Isolate)
	Y	VI 48 : z_{10} : 1,5 (2 Isolate)
		VI 48 : z_{41} : -

OIPE JC56
JUN-18 2001
PATENT & TRADEMARK OFFICE

Sub-species	Sero-gr.	Salmonella Sero type
		II 17 : b : e, n, x, z_{15}
	L	II 21 : z_{10} : - (2 isolate)
	P	II 38 : d : 1,5 (2 isolate)
	R	II 1, 40 : z_{42}: 1,5,7 (2 isolate)
	S	II 41 : z_{10}, 1, 2 (2 isolate)
	T	II 42 : r : - (6 isolate)
	X	II 47 : a : 1,5 (2 isolate)

Sub-species	Sero-gr.	Salmonella Sero type
	J	IIIb 17 : z_{10}, e, n, x, z_{15} (2 isolate)
	O	IIIb 35 : k: e, n, z_{15} (2 isolate)
	P	IIIb 38 : l, v: z_{53}
		IIIb 38 : l, v: z_{54}
	T	IIIb 42 : k : z_{35} (2 isolate)
	X	IIIb 47 : b : z_8
		IIIb 47 : k : z_{35}

Sub-species	Sero-gr.	Salmonella Sero type
		IIIb 47 : r: z_{53}
		IIIb 47 : - : -
	Y	IIIb 48 : (k) : z_{53} (2 isolate)
	Z	IIIb 50 : k : z
		IIIb 50 : r : z
	O:53	IIIb 53 : l, k : z (2 isolate)
	O:60	IIIb 60 : z_{52} : z_{53}
	O:61	IIIb 61 : i : z
		IIIb 61 : l, v : 1,5,7
		IIIb 61 : l, v : 1,5,7: (z_{57})
		IIIb 61 : r : z_{53}
S. enterica subsp. *houtenae*	F	IV 11 : z_4, z_{23}: - (2 isolate)
	I	IV 16 : z_4, z_{32}: -(3 isolate)
	I	IV 16 : z_4, z_{32}: - (2 isolate)
	J	IV 17 : z_{29}: - (2 isolate)
	K	IV 18 : z_{36}, z_{38}: - (2 isolate)
	L	IV 21: g, z_{51}: - (3 isolate)
	U	IV 43 : z_4, z_{23}: - (3 isolate)
		IV 43 : z_4, z_{32}: -
	V	IV 44 : z_4, z_{32}: - (3 isolate)
	Y	IV 48 : z_{29}: - (2 isolate)
	Z	IV 50 : z_4, z_{23}:- (2 isolate)
S. enterica subsp. *indica*	S	VI 41 : b: 1,7 (2 isolate)
	W	VI 45 : a: e,n,x, (z_{17}) (2 isolate)
	Y	VI 48 : z_{10} : 1,5 (2 isolate)
		VI 48 : z_{41} : -

OIPE JC59
JUN 18 2001
PATENT & TRADEMARK OFFICE

Sub-species	Sero-gr.	Salmonella Sero type
		VI l, v : z_{67}
S. bongori	R	V 40 : z_{35}: - (4 isolate)
		V 40 : z_{61}: -
	V	V 44 : d: -
		V 44 : z_{39}: - (4 isolate)
	Y	V 48 : z_{35}: - (4 isolate)

The strains listed in tables 1-3 have been tested with the PCR test kit „foodproof™ Salmonella" of BIOTECON Diagnostics. This detection system is based on primers and probes SEQ ID 1-10 of US application 09/485 434.

Dr. Pia Scheu further declares that all statements made herein of her own knowledge are true, and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like, so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the US Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Potsdam (Germany), 05/15/01

Dr. Pia Scheu

12.JUN.2001 18:49 +49 89 653962 BOETERS & BAUER #1852 P.031

EPO JUN 18 2001 PATENT & TRADEMARK OFFICE

Community legislation in force

Document 392L0118

Directory chapters where this document can be found:
[03.50.30 - Animal health and zootechnics]

Instruments amended:
392L0046 (Modification)
390L0667 (Modification)
390L0425 (Modification)
389L0662 (Modification)
377L0099 (Modification)
372L0461 (Modification)

392L0118
Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC
Official Journal L 062 , 15/03/1993 p. 0049 - 0068
Finnish special edition....: Chapter 3 Volume 48 p. 194
Swedish special edition....: Chapter 3 Volume 48 p. 194

Amendments:
Amended by 194N
Amended by 394D0466 (OJ L 190 26.07.1994 p.26)
Amended by 394D0723 (OJ L 288 09.11.1994 p.48)
Amended by 395D0338 (OJ L 200 24.08.1995 p.35)
Amended by 395D0339 (OJ L 200 24.08.1995 p.36)
Amended by 396D0103 (OJ L 024 31.01.1996 p.28)
Amended by 396D0340 (OJ L 129 30.05.1996 p.35)
Amended by 396D0405 (OJ L 165 04.07.1996 p.40)
Amended by 396L0090 (OJ L 013 16.01.1997 p.24)
Amended by 397L0079 (OJ L 024 30.01.1998 p.31)
Amended by 399D0724 (OJ L 290 12.11.1999 p.32)

Text:

COUNCIL DIRECTIVE 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC
THE COUNCIL OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Economic Community, and in

12.JUN.2001 18:47 +49 89 653962 BOETERS & BAUER #1852 P.026

OIPE JC59
JUN 18 2001
PATENT & TRADEMARK OFFICE

(b) each consignment is accompanied by a commercial document or certificate provided for in Article 13 (2) (b) of Directive 90/667/EEC stating that:
(i) the dried petfood consisted of products of slaughtered animals heat-treated so as to achieve a temperature throughout their substance of at least 90 °C, on the understanding that the treatment was not necessary for finished products the ingredients of which had undergone such treatment;
(ii) after heat treatment, every precaution was taken to ensure that the product was not contaminated in any way prior to shipment;
(iii) the product is packed in new containers (bags or sacks);
(iv) the production process has been tested, with satisfactory results, in accordance with Chapter III (2) of Annex II to Directive 90/667/EEC.
4. Each consignment of products manufactured from processed hides must be accompanied by a commercial document or certificate provided for in Article 13 (2) (b) of Directive 90/667/EEC stating that the products have been subjected to a heat treatment during processing sufficient to destroy pathogenic organisms (including salmonella) and that effective steps were taken after processing to prevent contamination of the products.
CHAPTER 5
Bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal)
Trade in and imports of the products in question are subject to the following conditions:
A. where they are intended for human or animal consumption:
1. where trade is concerned, bones, horns and hooves are subject to the animal health requirements laid down in Directive 72/461/EEC;
2. where trade is concerned, bone products, horn products and hoof products are subject to the animal health requirements provided for in Directive 80/215/EEC (2);
3. where imports are concerned, bones, bone products, horns, horn products, hooves and hoof products are subject to the requirements of Directive 72/462/EEC (3);
B. where they are intended for uses other than human or animal consumption, including those intended to be processed with a view to the manufacture of gelatins:
1. Member States shall authorize the importation of bone and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (exluding hoof meal) provided that:
(i) the products are dried before export and not chilled or frozen;
(ii) the products are conveyed only by land and sea from their country of origin direct to a border inspection post in the Community and are not transhipped at any port or place outside the Community;
(iii) following the document checks provided for in Directive 90/675/EEC, the products are conveyed directly to the manufacturing plant;
2. each consignment must be accompanied by an undertaking from the importer that products imported under this chapter will not be diverted for direct use in human or animal food.
A declaration to this effect must be presented to the official veterinarian at the border inspection post at first point of entry of the goods into the Community and be annotated by him, and thereafter shall accompany the consignment to its destination.
3. under the procedure provided for in Article 18 of this Directive, in the light of the animal health situations and guarantees as regards controls on origin offered by a third country, derogations from some of these requirements may be permitted.
CHAPTER 6
Processed animal protein
I. Without prejudice to any restrictions imposed as regards BSE or to the restrictions on the feedings of ruminant protein to ruminants, trade in and imports of processed animal protein are subject:
A. as regards trade:
- in processed animal protein intended for human foodstuffs, to the production of the document or certificate provided for in Directive 77/99/EEC stating that the requirements

12.JUN.2001 18:47 +49 89 653962 BOETERS & BAUER #1852 P.027

OIPE JC59 JUN 18 2001 PATENT & TRADEMARK OFFICE

of that Directive have been complied with,
- in processed animal proteins intended for animal feedingstuffs, to the production of the document or certificate provided for in Article 13 of Directive 90/667/EEC;

B B. as regards imports:

1 1. to production of a health certificate as provided for in Article 10 (2) (c), signed by the official veterinarian of the country of origin and stating that:

(a) the product:

(i) where it is intended for animal consumption, has undergone appropriate heat treatment with the result that it complies with the biological standards laid down in Annex II, Chapter III to Directive 90/667/EEC;

(ii) where it is intended for human consumption, fulfils the requirements of Directive 80/215/EEC;

(b) every precaution has been taken after treatment to prevent contamination of the product treated;

c (c) samples have been taken and tested for salmonella when the consignment left the country of origin;

d (d) the results of these tests are negative;

2. following document checks of the certificate referred to in 1, to sampling by the competent authority at the border inspection post without prejudice to point II:

(i) of each consignment of products submitted in bulk;

(ii) at random of consignments of products packaged in the manufacturing plant;

3. for release for free circulation in Community territory of consignments of processed animal protein, to prove that the results of the sampling carried out pursuant to B (1) (c) have proved negative, if necessary after reprocessing;

C. national rules existing on the date of notification of this Directive concerning the requirements applicable as regards BSE and scrapie for animal proteins may be maintained pending a decision on the type of heat treatment capable of destroying the agent responsible.

Trade in and imports of meat meal and bone meal remain subject to Article 5 (2) of Directive 89/662/EEC and Article 11 (2) of Directive 90/675/EEC.

II. Member States may carry out random sampling of bulk consignments originating in a third country from which the last six consecutive tests have proved negative. Where during one of these checks a result has proved positive, the competent authority of the country of origin must be informed so that it can take appropriate measures to remedy the situation. These measures must be brought to the attention of the competent authority responsible for the import checks. In the event of a further positive result from the same source, further tests must be carried out on all consignments from the same source until the requirements laid down in the first sentence are again satisfied.

III. Member States must keep records of the results of sampling carried out on all consignments which have undergone sampling.

IV. In accordance with Article 3 (3) of Directive 89/662/EEC, transhipment of consignments is permitted only through ports which have been approved under the procedure laid down in Article 18, provided that a bilateral agreement has been reached between Member States to allow checking of the consignments to be deferred until they reach the border inspection post of the Member State of final destination.

V. Where a consignment proves to be positive for salmonella, it is either:

(a) re-exported from the Community;

(b) used for purposes other than animal feeds. In this case, the consignment may leave the port or storage depot only on condition that it is not incorporated into animal feedingstuffs;

(c) re-processed in a treatment plant approved pursuant to Directive 90/667/EEC or any plant approved for decontamination. Movement from the port or storage depot shall be controlled by permit from the competent authority and the consignment shall not be released until it has been treated, tested for salmonella by the competent authority in accordance with Annex II, Chapter III, to Directive 90/667/EEC and a negative result

12.JUN.2001 18:48 +49 89 653962 BOETERS & BAUER #1852 P.028

OIPE JC56 JUN 18 2001 PATENT & TRADEMARK OFFICE

(2) (c).

CHAPTER 12

Apiculture products

1. Apiculture products intended exclusively for use in apiculture:

(a) must not come from an area which is the subject of a prohibition order associated with an occurrence of American foulbrood or acarioasis, if in the case of acarioasis the Member State of destination has obtained additional guarantees in accordance with Article 14 (2) of Directive 92/65/EEC (7);

(b) must meet the requirements imposed by Article 8 (a) of Directive 92/65/EEC.

2. Any derogations must be established, as necessary, under the procedure laid down in Article 18 of this Directive.

CHAPTER 13

Game trophies

Trade in and imports of untreated game trophies must be accompanied by the commercial document provided for in the last indent of Article 4 (2) (a) or by the health certificate provided for in Article 10 (2) (c) stating that:

1. the trophies in question do not come from animals originating in an area subject to restrictions as a result of the presence of serious transmissible diseases;

2. the trophies in question are completely dry and without residual meat and that they were dried or dry-salted or wet-salted for at least 14 days before they were dispatched;

3. the consignment has not been in contact with any other product of animal origin or any animal likely to contaminate it;

4. once dry, the product was disinfected with products authorized by the competent authority of the dispatching country;

5. the trophies were packaged in new, transparent packaging.

CHAPTER 14

Manure for treatment of the soil (8)()

Processed manure products

All organic fertilizers have been treated to ensure that the product is free from pathogenic agents.

Treated manure products meeting the following requirements may be the subject of trade or imports:

- exempt from salmonella:

absence of salmonella in 25 g of treated product;

- exempt from enterobacteriaceae:

based on the aerobic bacteria count (< 1 000 cfu per gram of treated product);

- reduced level of spore-forming bacteria and toxin formation:

moisture content < 14 %, product aW value < 0,7.

Products must be stored in such a way that, once processed, contamination or secondary infection and dampness is impossible.

Products must therefore be stored in:

- well-sealed and insulated silos, or
- properly sealed packs (plastic bags or 'big bags').

Unprocessed manure

Only unprocessed manure from chicken and equidae may be the subject of trade or import. This manure must originate in a region free of serious transmissible animal diseases, in particular:

- foot-and-mouth disease,
- Newcastle disease,
- swine fever,
- avian influenza,
- African swine fever,
- African horse sickness,
- swine vesicular disease.

If necessary, bacteriological standards may be established under the procedure laid down

12.JUN.2001 18:48 +49 89 653962 BOETERS & BAUER #1852 P.029